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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,580	11/08/2001	Robin Thurmond	ORT-1458	4339

7590 10/03/2003

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EXAMINER	
MOORE, WILLIAM W	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/010,580	THURMOND ET AL.	
	Examiner	Art Unit	
	William W. Moore	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-13 is/are pending in the application.

4a) Of the above claim(s) 7,8,12 and 13 is/are withdrawn from consideration.

5)☒ Claim(s) 1-6 and 9 is/are allowed.

6)☒ Claim(s) 10 and 11 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-13 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. §121:

1. Claims 1-5 and 9, drawn to an isolated polynucleotide comprising the sequence set forth in SEQ ID NO:1, an expression vector comprising it, host cells comprising the vector, and a recombinant method of making an encoded polypeptide using the vector, classified, *inter alia*, in class 536, subclass 23.2 .

2. Claims 6, 10, and 11, drawn to a substantially pure canine Cathepsin S protease comprising the amino acid sequence set forth in SEQ ID NO:2 and a method of using the protease in an assay to identify compounds that modulate its activity, classified, *inter alia*, in class 435, subclass 226.

3. Claims 7 and 8, drawn to a monospecific antibody capable of specifically binding to a canine Cathepsin S protease, classified in class 530, subclass 387.1.

4. Claims 12 and 13, drawn to a pharmaceutical composition comprising an unspecified compound capable of modulating the proteolytic activity of a canine Cathepsin S protease and a method of using the composition in treating a patient by administering the composition, classified in class 514, subclass 1.

The inventions are distinct, each from the other, because of the following reasons:

Inventions of Group 1 and Group 2 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process.

Inventions of Group I and Groups 3 and 4 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, functions, and effects.

Inventions Group 2 and Groups 3 and 4 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions different modes of operation, functions, and effects.

Inventions Group 3 and Group 4 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes

of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions different modes of operation, functions, and effects.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification restriction for examination purposes as indicated is proper.

During a telephone conversation with Ms. Linda S. Evans on June 25, 2003, a provisional election was made with traverse to prosecute the invention of Group 1, claims 1-5 and 9. Affirmation of this election must be made by applicant in replying to this Office action. In view of the fact that the subject matter of claim 6 is a singular species of polypeptide and that a search of the prior art established the patentability of the invention of Group 1 and showed that the protease having the amino acid sequence set forth in SEQ ID NO:2 is free of the prior art, the requirement for restriction as between Groups 1 and 2 is hereby RESCINDED, but the requirement for restriction as between Groups 1 and 2 and Group 3 or Group 4 is maintained. Claims 8, 9, 12 and 13 are therefore withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR §1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR §1.48(b) and by the fee required under 37 CFR §1.17(h).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10 and 11 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 10 and 11 are jointly rejected because specification neither exemplifies nor describes the preparation of generic canine cathepsin S proteases for the practice of the methods of claims 10 and 11 and neither the claims nor the specification describe where any differences may occur between the amino acid sequence set forth in SEQ ID NO:2 and some other cathepsin S present in any dog nor what the differences might be. The specification does not otherwise disclose or suggest the nature or source of any of the generic canine cathepsin S proteases that permit the practice of the methods of claims 10 and 11. Claim 11 is independently rejected because the specification does not exemplify, describe or discuss a method of identifying modulatory compounds that have an "effect" on a disclosed protease of "enhancing cysteine protease activity." The specification instead provides only a method of identifying modulatory compounds that can have an effect on a disclosed protease of inhibiting cysteine protease activity. "While one does not need to have carried out one's invention before filing a patent application, one does need to be able to describe that invention with particularity" to satisfy the description requirement of the first paragraph of 35 U.S.C. §112. *Fiers v. Revel v. Sugano*, 25 USPQ2d 1601, 1605 (Fed. Cir. 1993). The specification furnishes no relevant identifying characteristics of a protease that diverges from the sequence of SEQ ID NO:2, nor does it provide any disclosure of a method for identifying enhancers of cysteine protease activity. Nothing demonstrates that, at the time the specification was filed, Applicant was "able to envision" enough of the structure of any of these undisclosed generic proteins to provide the public with identifying "characteristics [that] sufficiently distinguish it . . . from other materials". *Fiers*, 25 USPQ2d at 1604 (citing *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991). The specification's treatment of the claimed subject matter is considered to be entirely prospective where skilled artisans in the relevant field of molecular biology could not predict the structure of a generic cathepsin S protease with

which to practice methods of claims 10 and 11 or determine how a disclosed method of identifying inhibitors of cysteine protease activity can extend to methods of identifying enhancers of cysteine protease according to claim 11.

Allowable Subject Matter

Claims 1-6 and 9-11 are free of the prior art of record herein which fails to disclose or suggest either the nucleic acid sequence set forth in SEQ ID NO:1, the canine cathepsin S protease amino acid sequence set forth in SEQ ID NO:2, or the availability of a canine cathepsin S with which to practice a method of claims 10 and 11. Because claims 1-6 and 9 raise no issues under the first or second paragraph of 35 U.S.C. §112, they are allowed herewith. The subject matters of claims 1-6 and 9-10 have the specific utility discussed at page 4, lines 9-13, of the specification and demonstrated in Example 4 at page 49 of the specification and in Figure 4, which utility is substantial as evidenced by the disclosures at pages 1-3 of the specification and by the prior art made of record in Applicant's Information Disclosure filed with the specification on December 11, 2001, as well as the prior art made of record herewith. This utility is also credible in view of the 78.6% amino acid identity shared by the amino acid sequence of the human cathepsin S and the canine cathepsin S having the amino acid sequence of SEQ ID NO:2 herein, as well as the high degrees of sequence identities the disclosed canine cathepsin S amino acid sequence shares with the amino acid sequences of mouse and rat cathepsins S, respectively, 68.5% and 66.8% and also in view of the fact that mammalian cathepsins S have a well-established biological activity in proteolytic maturation of invariant chains of major histocompatibility complex [MHC] class II molecules in endosomes of cells of the immune defense system, an activity that is required for recognition of foreign peptides by MHC class II molecules and the absence of which contributes to mammalian immune system disorders, see, e.g.,

Chapman et al., WO 99/58153, and Kirschke et al.(1986), made of record with Applicant's Information Disclosure Statement.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 703.308.0583. The examiner can normally be reached between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at 703.308.3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703.308.4242 for regular communications and 703.308.0294 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0196.

William W. Moore
September 30, 2003

NASHAAT T. NASHED PHD.
PRIMARY EXAMINER